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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
ORLANDO DIVISION

ROBERT DANIEL TAYLOR,

Plaintiff,

Case No. 6:18-cv-013-ORL-31-DCI

v.

LEANNE POLHILL; RANDY ELLSWORTH;
ROBERT PICKARD, MD; JOHN FISCHER;
DOUGLAS MOORE; PAMELA
DECMEROWSKI; MARIA HERNANDEZ;
and THOMAS HOLLERN; each solely in their
official capacities as Members of the Florida
Board of Hearing Aid Specialists; CELESTE
PHILIP, MD, MPH, solely in her official
capacity as Secretary of the Florida Board of
Health,

**COMPLAINT FOR
DECLARATORY AND
INJUNCTIVE RELIEF**

Defendants.

1. Plaintiff Robert Daniel (Dan) Taylor, by and through his undersigned counsel, brings this constitutional lawsuit for declaratory and injunctive relief, and alleges as follows:

INTRODUCTION

2. Hearing loss affects an estimated 30-million people across America. Yet many of those people lack access to hearing aids, because onerous, outdated, and unconstitutional regulations limit who may sell them and impose conditions on

their sale, which decreases their availability and increases the cost of obtaining them. This case seeks to vindicate the right of Plaintiff Dan Taylor to sell hearing aids to Florida consumers subject only to regulations that are not preempted by federal law and which are rationally related to a legitimate governmental purpose.

3. For more than 30 years, Dan has earned his livelihood selling hearing aids in the State of Florida as a licensed Hearing Aid Specialist. He declined to renew his license last year because he believed the state's requirements that he use antiquated procedures and equipment in the sale of hearing aids unnecessarily burdened his business and prevented him from rendering the best service to his customers. He has sold, and wishes in the future to sell, state of the art hearing aids that use modern software and hardware. These new technologies allow consumers to select hearing aids and have them fitted with common tools, including personal computers or smartphones.

4. Selling a hearing aid without a license has been declared a serious crime in Florida, as is failing to use the state's mandated procedures and equipment as part of the sales process. However, no license is required by federal law to sell hearing aids, and state regulation inconsistent with federal conditions on the sale of hearing aids is expressly preempted by the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetics Act. Moreover, Florida's mandated procedures and equipment are unreasonable in light of advances in technology since its statutes

were enacted. This case therefore raises federal questions under the U.S. Constitution's Supremacy Clause and the Due Process Clause of the Fourteenth Amendment.

5. Florida's regulations require Dan to suspend his business to avoid punishment by the state. He will suffer lost business and the deprivation of his constitutional rights unless the state laws challenged herein are declared unconstitutional and Defendants are enjoined from enforcing them. This action seeks wholly prospective declaratory and injunctive relief and no monetary damages against any party.

JURISDICTION AND VENUE

6. This Court has jurisdiction pursuant to 28 U.S.C. §§ 1331 (federal question jurisdiction) & 1343 (jurisdiction to redress deprivations of civil rights), and the Civil Rights Act of 1871, 42 U.S.C. § 1983.

7. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b) and L.R. 1.02(c) because Plaintiff's residence and principal place of business is within Brevard County, and because the acts or omissions giving rise to this Complaint are occurring within this judicial district.

8. The Court has authority to provide the relief requested under the Supremacy Clause, U.S. Const. art. VI, cl.2, as well as 28 U.S.C §§ 2201 & 2202 (Declaratory Judgment Act), 42 U.S.C. § 1983, and its inherent equitable powers.

PARTIES

9. Plaintiff Dan Taylor is a United States citizen and resident of Brevard County, Florida, who has earned his livelihood selling hearing aids to consumers in Florida for more than 30 years.

10. Defendant Leanne Polhill is the Chair of the Florida Board of Hearing Aid Specialists. Defendant Randy Ellsworth is Vice-Chair of the Florida Board of Hearing Aid Specialists. Defendants Robert Pickard, John Fischer, Douglas Moore, Pamela Decmerowski, Maria Hernandez, and Thomas Holleran are Members of the Florida Board of Hearing Aid Specialists. As members of the Board, they are responsible for licensing and disciplining individuals engaged in the sale of hearing aids in the State of Florida, and for issuing regulations imposing conditions on the sale of hearing aids in the state.

11. Defendant Celeste Philip is Florida's Surgeon General and Secretary of the Florida Board of Health. In her capacity as Secretary of the Florida Board of Health she is charged with enforcing Florida statutes prohibiting the unlicensed sale of hearing aids in the state and issue citations imposing fines and other penalties.

12. All of the Defendants are sued solely in their official capacities pursuant to the doctrine established by *Ex parte Young*, 209 U.S. 123 (1908).

FACTUAL ALLEGATIONS

The Market for Hearing Aids

13. Hearing loss affects an estimated 30-million people in the United States, typically resulting in a diminished quality of life.

14. Hearing aids are medical devices regulated by the U.S. Food and Drug Administration (FDA), and are the most common means by which hearing-impaired individuals mitigate or cope with their condition.

15. A hearing aid is “any wearable instrument or device designed for, offered for the purpose of, or represented as aiding person with or compensating for, impaired hearing.” *See* 21 C.F.R. § 801.420 (FDA definition).

16. More than 3.5-million hearing aid devices have been sold each year in the United States during the past five years.

17. The FDA estimates, however, that only approximately one-fifth of those persons who could benefit from hearing aids actually use them.

18. A significant reason why so few benefit from needed hearing aids is state regulation of hearing aid sales, which impose burdensome or unnecessary “conditions of sale,” making it more difficult for consumers to access hearing aids, restrict who may sell the devices, and tend to increase the price of them to end consumers.

Federal Law Establishes Exclusive Conditions on the Sale of Hearing Aids

19. The federal government has established a comprehensive legal scheme regulating “conditions of sale” applicable to hearing aid devices.

20. The federal regulations aim to ensure the safety and effectiveness of hearing aids, while preserving easy access to devices by consumers and imposing minimal restrictions on dispensers of hearing aids.

21. The MDA of 1976 amended the Food, Drug, and Cosmetic Act (FDCA) of 1938, providing the U.S. Food and Drug Administration (FDA) with authority over medical devices, including hearing aids. *See* 21 U.S.C. § 321(h).

22. In enacting the MDA, Congress expressly preempted state laws that regulate hearing aids to impose conditions of sale “different from” or “in addition to” federal rules.

23. The FDA has promulgated regulations governing the sale of hearing aids, including who may purchase them and what conditions are imposed on dispensers who sell them.

24. The FDA’s conditions on the sale of hearing aids require that devices carry specific labeling and that manufacturers provide a brochure that includes product information (including technical information, information on where one may obtain repair service, and various warnings applicable to the dispenser and the consumer related to the use and functioning of the device). *See* 21 C.F.R.

§ 801.420(b)-(c). The FDA defines a “dispenser” of hearing aids to mean “any person, partnership, corporation, or association engaged in the sale, lease, or rental of hearing aids to any member of the consuming public.” 21 C.F.R. § 801.420(a)(3).

25. The FDA regulations require hearing aid dispensers to be aware of eight “red flags” and, if a dispenser learns about one of these flags by observation or by other information, he must “advise a prospective hearing aid user to consult promptly with a licensed physician” prior to sale of a hearing aid. Those red flags are: visible congenital or traumatic deformity of the ear; history of active drainage from the ear within the previous 90 days; history of sudden or rapid hearing loss within the previous 90 days; acute or chronic dizziness; unilateral hearing loss of sudden or recent onset within the previous 90 days; visible evidence of significant cerumen accumulation or a foreign body in the ear canal; a difference in “audiometric air-bone gap” equal to 15 decibels or greater measured at various frequencies; pain or discomfort in the ear. *See* 21 C.F.R. § 801.420.

26. Further, the FDA rules prohibit “a hearing aid dispenser” from selling “a hearing aid unless the prospective user has presented to the hearing aid dispenser a written statement signed by a licensed physician” that the patient has been evaluated within the prior six months and deemed a candidate for a hearing aid, or unless the patient is over the age of 18 and signs a “waiver to the medical evaluation requirements.” 21 C.F.R. § 801.421(a).

27. Additionally, the FDA rules require a hearing aid dispenser to retain a copy of either the waiver noted in paragraph 26 or the written statement from the physician noted in paragraph 26.

28. No presale audiometric testing (tests measuring the acuity of hearing) is required as a condition of sale on hearing aids by the MDA or FDA regulations or any other federal law.

29. According to the MDA's express preemption clause, "no State or political subdivision of a State may establish or continue in effect with respect to a device . . . any requirement" that is (1) "different from, or in addition to any requirement applicable" under federal law, and "(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device." 21 U.S.C. § 360(a).

30. In December, 2016, the FDA issued guidance modifying the "Conditions for Sale for Air-Conduction Hearing Aids" to "communicate to consumers, hearing aid dispensers, hearing aid manufacturers, and hearing health professions that the FDA does not intend to enforce certain conditions for sale of hearing aids that are required per FDA regulation." In particular, the FDA no longer enforces "the medical evaluation (21 C.F.R. § 801.421(a)) or recordkeeping (21 C.F.R. § 801.421(d)) requirements prior to the dispensing of" FDA-approved

“Class I air-conduction hearing aids” and “Class II wireless air-conduction hearing aids” to persons over the age of 18.¹

31. Upon information and belief, and according to the FDA and the National Academies of Sciences, Engineering and Medicine, the medical evaluation requirement “provides no clinically meaningful benefit [to consumers]” and the need to affirmatively waive the requirement “presents a barrier to access with no substantial enhancement of patient safety.”

32. Air-conduction hearing aids designated by the FDA as “Class I” hearing aid devices are deemed by the FDA to present the lowest risk of harm to consumers; similarly classified “Class I” medical devices include dental floss and tongue depressors.

33. Some wireless air-conduction hearing aids are regulated as “Class II” medical devices by the FDA, requiring manufacturers to obtain premarket approval by the agency. FDA-approved “Class II” hearing aids pose de minimis risks to consumer health or safety; similarly classified “Class II” medical devices include motorized wheelchairs.

¹ See <https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm531995.pdf>.

**Defendants Impose Additional and Unlawful Conditions on the Sale of
Hearing Aids in Florida**

34. Notwithstanding the federal law and FDA regulations establishing exclusive conditions of sale on the dispensing of hearing aids, Florida deems the dispensing of hearing aids to be a privilege granted by the state.

35. Florida law defines the “dispensing of hearing aids” broadly, as “[a]ll acts pertaining to the selling, renting, leasing, pricing, delivery, and warranty of hearing aids.” Fla. Stat. § 484.041(3). According to Florida law, dispensing includes “interpreting hearing tests for purposes of selecting suitable hearing aids, making earmolds or ear impressions, and providing appropriate counseling.” *Id.*

36. No one may dispense hearing aids in Florida “unless the person is a licensed hearing aid specialist.” Fla. Stat. § 484.053.

37. Obtaining a hearing aid specialist license requires six months of training, license fees, and successful examination by the Florida Board of Health, and must be maintained by continuing education and fees. Fla. Stat. §§ 484.0445, 484.0447, 484.045, 484.047.

38. Neither federal law nor FDA regulations require hearing aid dispensers to be licensed; Florida’s requirement that only licensed persons dispense hearing aids is different from and in addition to rules promulgated by the MDA and related FDA regulations and is expressly preempted by federal law.

39. Florida law prohibits the sale of hearing aids without a “fitting,” using particular procedures and equipment prescribed by statute and regulation to ensure the effectiveness of the hearing aid. Fla. Stat. § 484.0501. Those minimum procedures include:

- An audiometric test measuring pure tone air-conduction thresholds with measurements from 250 Hz to 8,000 Hz, with masking.
- An audiometric test measuring pure bone-conduction thresholds using a bone-conduction oscillator with measurements from 500 Hz, 1,000 Hz, and 2,000 Hz, with masking.
- Consumers determined to have a significant difference between bone-conduction and air-conduction hearing must be informed of the possibility of medical correction.
- Testing to determine speech reception thresholds, speech discrimination scores, most comfortable listening levels, uncomfortable loudness levels.
- Otoscopy to inspect the ear canal and interrogation of the consumer to learn recent health history.
- At the time of initial examination for fitting and sale of a hearing aid, a licensed hearing aid specialist must notify the prospective purchaser of the benefits of certain hearing aid technology.

40. Neither federal law nor FDA regulations requires a “fitting” of a hearing aid or require audiometric testing prior to sale. Florida’s requirement of a presale fitting, and the particular minimum procedures mandated by Fla. Stat. § 484.0501, are different from and in addition to rules promulgated by the MDA and related FDA regulations and are expressly preempted by them.

41. Further, Florida law requires that the above minimum procedures be conducted using particular equipment, Fla. Stat. § 484.0501, and mandates that:

- Testing shall be done using a currently calibrated wide range audiometer that meets the specifications of the American National Standards Institute.

- Testing shall be conducted using a speech audiometer or master hearing aid.

- Licensed hearing aid specialists conduct testing in a specially constructed testing room certified by the Florida Department of Health or by an agent approved by the department not to exceed particular sound pressure levels at specified frequencies.

42. Neither federal law nor FDA regulations requires audiometric testing of any kind prior to the sale of a hearing aid nor that it be done with any particular kind of equipment. Florida’s “equipment” mandates are different from and in

addition to rules promulgated by the MDA and related FDA regulations and expressly preempted by them.

43. Federal regulations establish a process by which a State or its political subdivision may seek a waiver of express preemptions of state regulatory actions imposed by the MDA (*see* 21 C.F.R. § 808.1(c)), but neither Florida nor its agencies have been granted such a waiver.

44. By becoming a Hearing Aid Specialist licensed by the State of Florida, one agrees to adhere to the Board of Hearing Aid Specialists rules and regulations for the dispensing of hearing aids.

45. A licensed Hearing Aid Specialist is subject to discipline for failing to dispense hearing aids using the procedures and equipment prescribed by Florida's law and Board of Hearing Aid Specialists regulations, including citations and fines of up to \$5,000. Fla. Stat. § 456.065.

46. Anyone dispensing a hearing aid without a hearing aid specialist's license is guilty of a third degree felony, and subject to a fine of \$5,000 and jail time of up to five (5) years for each violation. *See* Fla. Stat. §§ 775.083(1)(c) & 775.082(3)(e).

47. Upon information and belief, hearing aid dispensers violate Florida state law even when selling lawfully under federal law, pursuant to procedures promulgated by the MDA and related FDA regulations.

48. Florida law and Defendants violate the Supremacy Clause by imposing a licensure requirement for dispensers of hearing aids, requiring a presale “fitting,” and mandating minimum procedures and equipment in fitting and dispensing, because those requirements impose conditions on the sale of hearing aid devices that are different from or in addition to federal law.

49. Upon information and belief, the procedures and equipment for presale audiometric testing mandated by Fla. Stat. § 484.0501 are antiquated. They no longer represent the state of the art, and in fact, require procedures rendered wholly unnecessary by modern technology. Whatever rational basis may have existed for the regulation at the time of its enactment has been superseded by changes in hearing aid technology that render the particular procedures and equipment mandated by the law unnecessary or irrational.

50. Today, there are many means of effectively selecting and fitting a hearing aid available beyond those mandated by Florida’s regulations. Modern hearing aids include technology that allows hearing aid dispensers with minimal training to assist consumers in the selection of appropriate hearing aids without risk to consumer health and without performing the particular procedures or using the particular equipment mandated by Fla. Stat. § 484.0501.

51. Requiring sellers of hearing aids to engage in unnecessary testing or use procedures that serve no useful purpose in light of current hearing aid

technology irrationally burdens sellers' constitutional right to earn a living in the occupation of their choice.

Defendants Unlawfully Prohibit Mail Order and Internet Sales of Hearing Aids in Florida

52. Florida also prohibits all sales and distribution of hearing aids through the mail to an ultimate consumer, thereby barring the mail order or internet sale of hearing aid devices to Florida consumers. *See Fla. Stat. § 484.054.*

53. Anyone selling or distributing a hearing aid device by mail is guilty of a misdemeanor, and subject to a fine of \$500 and jail time of up to 60 days for each violation. *See Fla. Stat. §§ 775.083(1)(e) & 775.082(e)(4)(b).*

54. The mail order sales ban has the purpose and effect of prohibiting the sale of hearing aid devices in Florida by a person unlicensed by the state as a Hearing Aid Specialist.

55. The mail order sales ban has the purpose and effect of prohibiting the sale of hearing aid devices in Florida without prior fitting and testing by a Florida-licensed Hearing Aid Specialist.

56. Moreover, the prohibition on mail order sales to Florida consumers serves the purpose of protecting hearing aid dispensers licensed by the Board of Hearing Aid Specialists from competition from unlicensed sellers.

57. Federal law expressly preempts state regulation of the conditions of sale of hearing aid devices that are “different from, or in addition to” the MDA and related FDA regulations relating to the safety or effectiveness of the device. *See* 21 U.S.C. § 360(k).

58. Upon information and belief, Florida’s ban on mail order sales is aimed at ensuring the safety and effectiveness of hearing aids purchased by Florida consumers.

59. Section 484.054 is expressly preempted by the MDA and related FDA regulations because it effectively requires hearing aids to be sold in Florida only by state-licensed dispensers, which is a condition of sale different from and in addition to the conditions of sale established by federal law.

60. Section 484.054 is also expressly preempted by the MDA and related FDA regulations because it prohibits sale of hearing aids without performing state-mandated presale procedures aimed at assuring the effectiveness of the devices, which are conditions of sale different from and in addition to the conditions of sale established by federal law.

61. Further, the FDA, acting under authority delegated to it by Congress, has specifically determined that state regulation requiring presale audiometric testing, as Florida’s Hearing Aid Specialist License statute requires, is preempted by the MDA.

Plaintiff and His Business

62. Dan Taylor is an entrepreneur who was a licensed Hearing Aid Specialist for more than 30 years. He was previously a Florida Highway Patrol state trooper.

63. He was continuously licensed as a Hearing Aid Specialist by the Board of Hearing Aid Specialists from 1984 until his license expired in February, 2017.

64. During his years as a Hearing Aid Specialist, Dan dispensed hearing aids as an employee of various hearing aid retailers, and worked as an equipment representative selling hearing aids and related equipment to retailers.

65. In 1992, Dan opened his own hearing aid retail store, A Advanced Hearing Care, in downtown Melbourne, Florida. His business was successful and he moved it to a larger suite in the same building in 1994. He operated at that same location for more than 26 years.

66. In all of his years as a licensed Hearing Aid Specialist, Dan was never disciplined or sanctioned by the Board of Hearing Aid Specialists or any other administrative or law enforcement agency due to any consumer complaint.

67. For at least the past 10 years, Dan has sold only Class I and Class II air-conduction hearing aid devices and those are the only type of hearing aids he wishes to sell in the future.

68. As part of his process for dispensing hearing aids, Dan would engage in “fitting” to help customers select hearing aids.

69. Modern hearing aids of the type sold by Dan allow for fitting to be done using *in situ* audiometric testing. Modern firmware and software built into the devices allows for a fitting of a hearing aid to be performed to standards that are as good or superior to the minimum procedures and equipment mandated by the Florida laws challenged herein.

70. *In situ* audiometric testing is less time-consuming and more convenient for many consumers than the minimum procedures and equipment mandated by Defendants, and results in equal or greater consumer satisfaction than older methods of “fitting.”

71. Modern hearing aids allow for effective selection and fitting of hearing aids without the minimum procedures and equipment mandated by the Florida laws challenged herein.

72. The effective selection of hearing aids today can be done using personal computers and smartphones with minimal, non-medical training; some hearing aid models are designed to allow consumers themselves to fit their hearing aids for comfort using smartphone applications or with a PC using “Bluetooth” technology.

73. The more intrusive and time-consuming sales and fitting procedures mandated by Florida law tend to dissuade consumers from seeking information or engaging in the process to select a hearing aid.

74. Dan wants to provide the best service he can to consumers, and to effectively serve as many consumers as feasible. For this reason, he does not want to conduct hearing aid fitting according to the minimum procedures mandated by Florida law but instead wants to conduct his business using superior software and hardware available with modern hearing aids.

75. In 2017, after considering FDA guidance and reading about hearing aid licensing-related lawsuits in other states, Dan decided not to renew his Hearing Aid Specialists license and to continue his business.

The Government's Past Enforcement Action Against Plaintiff

76. On October 11, 2017, the Florida Board of Health issued a Notice to Cease and Desist "from practicing as a Hearing Aid Specialist in the State of Florida unless and until he is appropriately licensed by the Department."

77. The government's Notice indicated that practicing without a Hearing Aid Specialist license "constitutes a crime" subject to civil and criminal penalties, including significant jail time.

78. The government's cease-and-desist notice also came with a Citation, issued on October 11, 2017, for violations of Fla. Stat. §§ 456.072(1)(k)(dd);

484.053(1); and 456.065(2)(d) for practicing or attempting to practice or offering to practice as a Hearing Aid Specialist without an active Florida Hearing Aid Specialists license. In particular, “Robert Daniel Taylor offered a hearing aid exam, to fit hearing aids, and provide the hearing aid device” to an “undercover Department of Health investigator.” The citation imposed a fine of \$1,000 and costs in the amount of \$212.72. *See* Attachment A.

79. Dan acknowledged the citation and paid the fine and costs imposed by the citation. On November 6, 2017, he received a letter from the Florida Board of Health confirming payment of the fine and stating that “[t]his matter is now closed, effective today.” *See* Attachment B.

80. This action does not seek to challenge the government’s past enforcement action or fine. This lawsuit seeks wholly prospective declaratory and injunctive relief, allowing Dan to resume his business dispensing hearing aids in the future, free of unconstitutional burdens imposed by the laws challenged herein.

INJURY TO PLAINTIFF

81. Dan is unable to pursue his livelihood selling hearing aids in Florida because Defendants prohibit the dispensing of hearing aids by anyone not licensed by the State of Florida as a Hearing Aid Specialist.

82. Dan is unable to conduct his business in the best way he knows how because Defendants and Florida law require he dispense hearing aids and provide

fitting services using antiquated procedures and equipment that constitute conditions on the sale of hearing aids different from and in addition to federal rules set out by the MDA and related FDA regulations.

83. Dan is unable to pursue his livelihood because Defendants have issued a cease-and-desist order threatening him with fines and other punishments, including jail time, for continuing to dispense hearing aids without a Hearing Aid Specialist license and without using the state's mandated procedures and equipment.

84. Dan is unable to pursue his plan of selling hearing aids through a website (via mail order) to Florida consumers because that activity is prohibited by Fla. Stat. § 484.054, challenged herein.

85. But for Florida's prohibition on the sale of hearing aids by persons not holding a valid Hearing Aid Specialists license, Dan would immediately begin dispensing hearing aids again in the state.

86. But for Florida's penalties for dispensing hearing aids without using its required fitting procedures and equipment, Dan would immediately begin dispensing hearing aids in the state using the modern techniques and equipment that he believes provide superior service to consumers.

CONSTITUTIONAL VIOLATIONS

Count I

(Federal Preemption as to Fla. Stat. § 484.053 & Fla. Stat. § 484.0501)

87. Plaintiff re-alleges and incorporates by reference each and every allegation set forth in paragraphs 1 through 86 of this Complaint as if fully set forth herein.

88. Fla. Stat. § 484.053 prohibits anyone who is not licensed by the State of Florida as a Hearing Aid Specialist from dispensing hearing aids in the State of Florida.

89. Fla. Stat. § 484.0501 require that licensed Hearing Aid Specialists dispense hearing aids dispensed using particular selection and fitting procedures and equipment, including presale audiometric testing, subject to penalty including fines and jail time for noncompliance.

90. Federal law expressly preempts state regulation of the conditions of sale of hearing aid devices that are “different from, or in addition to” the MDA and related FDA regulations relating to the safety or effectiveness of the device. *See* 21 U.S.C. § 360(k). Fla. Stat. §§ 484.053 and 484.0501 are aimed at ensuring the safety and effectiveness of hearing aids sold in Florida.

91. Fla. Stat. §§ 484.053 and 484.0501 impose conditions on the sale of hearing aids that are different from or in addition to conditions of sale established by the MDA and related FDA regulations.

92. Fla. Stat. §§ 484.053 and 484.0501 are in conflict with the MDA and related FDA regulations, including federal law expressly preempting such conflicting state laws. *See* 21 U.S.C. § 360(k).

93. Plaintiff is unable to pursue his livelihood dispensing hearing aids, even though he complies with all federal laws applicable to the dispensing of hearing aids, due to Florida's conflicting laws.

94. Unless Defendants are enjoined from enforcing these state laws, Plaintiff will be forced to close his business and continue to suffer great and irreparable harm.

95. Plaintiff therefore seeks declaratory and injunctive relief, preventing Defendants from enforcing Fla. Stat. § 484.053 and Fla. Stat. § 484.0501 on grounds that these statutes are expressly preempted by federal law and in violation of the Supremacy Clause of the U.S. Constitution.

Count II

(Federal Preemption as to Fla. Stat. § 484.054)

96. Plaintiff re-alleges and incorporates by reference each and every allegation set forth in paragraphs 1 through 95 of this Complaint as if fully set forth herein.

97. Fla. Stat. § 484.054 prohibits all sales and distribution of hearing aids through the mail to an ultimate consumer in Florida, subject to civil and criminal penalties.

98. The mail order sales ban has the purpose and effect of prohibiting the sale of hearing aid devices in Florida by a person unlicensed by the state as a Hearing Aid Specialist.

99. The mail order sales ban has the purpose and effect of prohibiting the sale of hearing aid devices in Florida without prior fitting and testing by a Florida-licensed Hearing Aid Specialist.

100. Federal law expressly preempts state regulation of the conditions of sale of hearing aid devices that are “different from, or in addition to” the MDA and related FDA regulations relating to the safety or effectiveness of the device. *See* 21 U.S.C. § 360(k).

101. The state's prohibition against sales of hearing aids by persons not licensed by Florida as Hearing Aid Specialists and its requirement of presale fitting and audiometric testing are in conflict with the MDA and related FDA regulations.

102. Plaintiff is unable to pursue his plan of selling hearing aids to Florida consumers through the internet and by mail, even though he complies with all federal laws applicable to the dispensing of hearing aids, due to Florida's conflicting laws.

103. Unless Defendants are enjoined from enforcing Fla. Stat. § 484.054, Plaintiff will continue to suffer great and irreparable harm.

104. Plaintiff therefore seeks declaratory and injunctive relief, preventing Defendants from enforcing Fla. Stat. § 484.054 on grounds that this statute is expressly preempted by federal law and in violation of the Supremacy Clause of the U.S. Constitution.

Count III

(Due Process as to presale requirements imposed by Fla. Stat. § 484.0501)

105. Plaintiff re-alleges and incorporates by reference each and every allegation set forth in paragraphs 1 through 104 of this Complaint as if fully set forth herein.

106. The Due Process Clause of the Fourteenth Amendment to the U.S. Constitution protects the right of every American to pursue legitimate

occupations, subject only to regulations that are rationally related to a legitimate governmental purpose.

107. Fla. Stat. § 484.0501 imposes “minimum procedures and equipment” requirements conditioning the sale of the type of Class I and Class II FDA-regulated hearing aids sold by Plaintiff.

108. Modern technology has rendered Florida’s minimum procedures and equipment requirements unnecessary to the selection and fitting of hearing aids.

109. There is no rational basis for requiring a presale audiometric test as a condition of hearing aid sales to consumers.

110. There is no rational basis for requiring audiometric testing or the fitting of hearing aids to be conducted according to the minimum procedures established by Fla. Stat. § 484.0501.

111. There is no rational basis for prohibiting anyone from lawfully dispensing a hearing aid consistent with the conditions of sale established by the MDA and related FDA regulations.

112. If there was at one time a rational basis for requiring presale audiometric testing, and particularly the audiometric testing mandated by Fla. Stat. § 484.0501, advances in hearing aid technology present changing circumstances that render Florida’s mandates irrational today.

113. Unless Defendants are enjoined from enforcing Fla. Stat. § 484.0501, Plaintiff will suffer great and irreparable harm by being denied his right to pursue the occupation of his choosing free of unnecessary and unreasonable governmental interference.

114. Plaintiff therefore seeks declaratory and injunctive relief, preventing Defendants from enforcing Fla. Stat. § 484.0501 on grounds that this statute violates the Due Process Clause of the Fourteenth Amendment.

REQUEST FOR RELIEF

Wherefore, Plaintiff requests judgment as follows:

A. A declaration that Fla. Stat. §§ 484.053, 484.054, and 484.0501, are unconstitutional on their face and as applied to the sale of Class I and Class II air-conduction hearing aids by Plaintiff and others similarly situated;

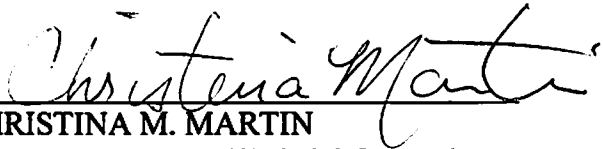
B. An injunction permanently enjoining Defendants from enforcing Fla. Stat. §§ 484.053, 484.054, and 484.0501, to the extent they violate the Supremacy Clause and Plaintiff's constitutionally protected due process right to earn a living free of unreasonable governmental interference;

C. An award of attorneys' fees, costs, and expenses in this action pursuant to 42 U.S.C. § 1988; and

D. All further legal and equitable relief as the Court may deem just and proper.

DATED: April 18, 2018.

Respectfully submitted:

By 
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***Special Admission Applications Pending**